I welcome you all to this first edition of our newsletter for 2015, and take the opportunity to review the European approval obtained on 22nd December 2014. The Australian press has sufficiently highlighted the fact that SCENESSE® (afamelanotide 16mg) has been the first new molecular entity in Australia which has been taken from preclinical to commercial stage. The challenges have been plentiful the past decade, and there are still some ahead of us, although the most difficult obstacles have been overcome.

A number of operational changes have been made to aid in the commercial distribution of SCENESSE® in Europe in 2015. We recently appointed Mr Willem Blijdorp as Non-Executive Director, part of transforming into a commercial entity. Further announcements, including the opening of a new UK operations office, are expected as our commercialisation plans are executed.

The European Medicines Agency’s (EMA’s) review – the longest scientific review for any orphan drug – reflected the complexity of Clinuvel’s challenge of obtaining approval for SCENESSE® in erythropoietic protoporphyria (EPP). Proving a novel concept had been far from easy despite the clinical efficacy reported by experts and patients, and the complex development and pathway was no surprise for our teams.

The approval process of SCENESSE® has entered the regulatory annals in that it was the first time that physicians’, academics’ and experts’ opinions, and patients’ experiences, were formally incorporated into the CHMP’s decision process. In simple terms, the lengthy review had been required to arrive at the knowledge that EPP was a unique disorder requiring a different approach from both the Company and the European regulator. Clinuvel rightly persisted to reach the final outcome.

Three months after European Commission ratification, Clinuvel is now the first company to have entered this field of photomedicine with a completely new pharmaceutical therapy.

The EMA approval of SCENESSE® is accompanied by a number of undertakings which have an impact on Clinuvel’s European distribution in 31 countries. Discussions with authorities, insurers and Ministries of Health have taken place and are ongoing to ensure Clinuvel complies with regulations in each individual country. Those countries where EPP patients are known obviously deserve the first attention, and those new territories will follow. The current climate in Europe is one where orphan drugs are being touted as urgent treatments for relatively few patients, while costs of healthcare need to be curtailed due to a growing and ageing population. Pharmaceuticals in the Eurozone make headlines while pricing of drugs has become a frequent topic of discussion. The five years of special access experienced in Italy and Switzerland had provided us valuable insight in the thinking of competent authorities in Europe and have laid the foundation for our
market access and pricing discussions.

The past months, our teams have given emphasis to the product release within the Eurozone. Once SCENESSE® reaches each country it is our task to assure a controlled distribution to porphyria expert centres, and we are therefore obliged to train physicians and clinical staff in the use of the product.

An important part of our distribution now and for longer term is the establishment of a porphyria patient registry, which includes both those patients who receive the drug and those who are not yet being treated. This exercise takes place at arm’s length since Privacy Acts, rules and regulations per country prohibit a pharmaceutical company from contacting patients directly or from storing medical records. These data need to be entered by each individual porphyria expert centre in a patient registry protected from third party intervention. This registry also ensures that each injected final product can be traced per patient and, if needs be, allows for product recall. At the same time, a national registry provides the ability to collect longer term data on patients.

The introduction of a new pharmaceutical product requires strict pharmacovigilance, since the safety of longer term use can only be obtained post-marketing authorisation. It is important for the patients, Company and national regulators to know the safety profile of the drug in, for instance, the first and second generation EPP patients. Monitoring of the pharmacovigilance brings along a management system which involves internal resources and the involvement of contract research organisations.

As distribution is being executed, each European country requires a different approach for adequate market access and pricing due to the individual national regulations applicable to specific medicinal products for orphan diseases. In summary, our teams have the task of characterising EPP for competent authorities, insurers and national authorities. Since we are introducing a novel treatment in a new formulation in a relatively unknown disorder, much needs to be explained. Some of the issues covered are the impact of the EPP on the lives of patients, the restriction posed by the disorder, and the magnitude of the handicap experienced. Here patients and physicians play a role, not dissimilar to their input during the latter stages of the EMA. The Company plays an active role in coordinating their input.

Another essential aspect of the market introduction is the definition of the treatment impact on patients. Here competent authorities and insurers are looking for utility scores, or in simpler terms for the daily benefit a patient receives from SCENESSE®.

As explained in the past and recently acknowledged by the EMA, EPP is such a distinct disorder that conventional measurements and instruments are insufficient to capture the magnitude of therapeutic benefit in patients.

EPP patients attribute much of the dramatic effects experienced while receiving SCENESSE® to a newly acquired freedom of choice for a life with normal activities, which had been unthinkable prior to treatment. Significantly, these effects are qualitative and far reaching.

A further requirement is to establish an inventory of known, diagnosed, adult EPP patients and undiagnosed unknown patients. This enables each individual country to budget for the treatment costs, but also aids Clinuvel and manufacturers to plan product manufacturing and supply.

At this stage of evolution, Clinuvel focuses on quality management systems, planning and pharmacovigilance. While we experience product demand from most of the European countries, the smaller nations will also deserve our attention. We will report in due course on the European roll out of SCENESSE®.

VITILIGO

The development plan for vitiligo bears similarities to the program for EPP in that Clinuvel has introduced a novel mode of action and new therapy in a disease once deemed untreatable.

The first proof of concept took place in the US in 2012 showing the efficacy of SCENESSE® in patients of darker skin, mainly African-Americans and Hispanics (Fitzpatrick skin types IV-VI). A second proof of concept is underway in Asia, where we aim to learn whether SCENESSE® is effective in vitiligo patients of Chinese, Indian and Malay origin. Singapore was identified for its breadth of potential skin types – with the three main ethnic groups constituting a diversity of types III-VI – and world class expert dermatology centre. At the same time, we are conscious of the limited resources to be spent on a proof of concept before conducting larger “registration trials” in the US.

Shortly a status on the vitiligo program will be given as well as the next steps to obtain registration for SCENESSE® in vitiligo.
Now that first European approval of SCENESSE® has been received, the development of CUV9900 as a follow-on product is being given full attention. Various parts of the development program are underway to establish it as a follow-on product in a number of skin disorders.

The approval of the first melanocortin tested in man serves as a foundation for further IP and internal knowhow on other members of this family of hormones and it is obvious that the knowledge gained from SCENESSE® greatly helped our teams for the design of the follow-on pipeline.

Proof of concept and preliminary safety and efficacy are being evaluated before we decide on the clinical positioning of CUV9900. Our teams will report on the preparation of the scientific dossier as the development progresses. We are aware of potential competitors watching our program in second generation products, accordingly we can only be sparse in revealing proprietary knowledge and knowhow.

Much lies ahead for Clinuvel’s teams in 2015. I thank the patients and expert physicians for their ongoing support of our program, and look forward to sharing further updates throughout the year.

Effective after the close of trade on March 20, Clinuvel will be added to the ASX All Ordinaries Index (XAO).

The All Ordinaries (or “all ords”) consists of the 500 largest companies by market cap listed on the ASX.

<table>
<thead>
<tr>
<th>Date</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>13-11-14</td>
<td>Clinuvel sets precedent with patients’ voices central to regulatory pathway – APMHealth</td>
</tr>
<tr>
<td>20-11-14</td>
<td>The Sunscreen Pill – Nature</td>
</tr>
<tr>
<td>22-12-14</td>
<td>European Commission approves Clinuvel Pharmaceuticals Ltd’s SCENESSE drug – Reuters</td>
</tr>
<tr>
<td>24-12-14</td>
<td>Light intolerance drug Scenesse gets special EU approval – Scrip</td>
</tr>
<tr>
<td>01-01-15</td>
<td>Aus dem Schatten hervortreten – Neue Zürcher Zeitung</td>
</tr>
<tr>
<td>09-01-15</td>
<td>Clinuvel’s tanning agent nears approval for porphyria – Nature Biotech</td>
</tr>
<tr>
<td>19-01-15</td>
<td>This man is allergic to sunlight – Irish Examiner</td>
</tr>
<tr>
<td>21-01-15</td>
<td>Exposure to sunlight burns my skin – now I can come out the shadows thanks to new drug – Bournemouth Echo</td>
</tr>
<tr>
<td>27-01-15</td>
<td>Clinuvel Update – Scenesse Launch Due April – Bioshares</td>
</tr>
<tr>
<td>09-02-15</td>
<td>Clinuvel’s afamelanotide likely to demonstrate superiority to light therapy alone in Phase IIb vitiligo study – experts – Biopharm Insight</td>
</tr>
<tr>
<td>17-02-15</td>
<td>Clinuvel’s Philippe Wolgen on Scenesse and the patient factor – Scrip</td>
</tr>
</tbody>
</table>


**RECENT CLINUVEL REPRESENTATION**

- XXII International Pigment Cell Conference – Singapore (Sept 4-7)
- 23rd EADV congress – Amsterdam (Oct 8-12)
- Porphyrias Consortium – Porphyrias Short Course – Galveston (Jan 30-31)

**ASX: CUV**

- Shares on issue: 44,554,787
- Average daily volume (past 3 months): 13,945
- Clinuvel is also listed on XETRA (UR9) and issued a level 1 ADR (CLVLY)
- Average Monthly Cash Burn Oct-Dec ’14: <A$0.64m
- Cash/Asset Balance at Dec 31 ’14: A$11.90m

**UPCOMING EVENTS**

- Skin of Color Society 11th Annual Meeting - San Francisco (Mar 19)
- Vitiligo Working Group meeting - San Francisco (Mar 19)
- 73rd Annual Meeting of the American Academy of Dermatology – San Francisco (Mar 20-24)
- 23rd World Congress of Dermatology – Vancouver (Jun 8-13)